(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 453 283 A1

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 91303469.0

(51) Int. Cl.[5]: A61B 5/00, C12M 1/40

(22) Date of filing: 18.04.91

(30) Priority: 19.04.90 US 511329

(43) Date of publication of application:
23.10.91 Bulletin 91/43

(84) Designated Contracting States:
AT BE CH DE DK ES FR GB GR IT LI LU NL SE

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(54) An integral interstitial fluid sensor.

(57) For application to the skin (12, 14) of a person or an animal for the detection of chemical components of tissue fluid, a fluid sensor (10) comprises a substrate (16) or a porous material for the passage of the interstitial fluid therethrough. At least two electrodes (18a, 18b) are provided. At least one of the electrodes (18a) has one side (20) mounted on the substrate (16). The electrode (18a) is also of a porous material and permits the passage of the interstitial fluid from one side through to the second side which is generally opposite the one side. A layer (24) of chemical is on the second side. The layer (24) of chemical comprises a chemical for reaction with one component of the fluid, mixed in a mediating agent. The electrodes (18a, 18b) generate an electrical signal upon the detection of the reaction of the one component of the fluid with the chemical. The electrical signal is received by an amperometric detector (32) and a display (34) is generated, indicating the amount of the one component detected. A pump (30) sucks the fluid from the skin (12, 14) into the sensor (10).

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The display of the amount of current in the electrical signal detected by the detector 32, indicates the amount of the one chemical component of the interstitial fluid.

In one embodiment, the sensor 10 is adapted to measure the glucose content of the interstitial fluid. The substrate 16 has the dimensions of approximately 2 to 4 Cm^2. The pump 30 applies a suction at a rate of approximately 200-400 torr. Each of the electrodes 18A or 18B can be 1mm. square. Thus, a total volume of approximately .01 microliter of the sensor 10 needs to be wetted. At a sampling rate of approximately .4 microliter/min/cm^2, the entire electrodes 18A and 18B can be wetted in less than 2 seconds. The chemical 24 is an enzyme glucose oxidase and the mediator is immobilized on the electrodes 18A and 18B. The thickness of the enzyme chemical layer 24 can be approximately 10 micrometer.

Using an amperometric detector 32, having a display 34, with a mediator, the sensor 10 of the present invention avoids buffer and oxygen dependency. As previously stated, the substrate 16 can be made of a porous material such as ceramic. Each of the electrodes can be made by sputtering metal upon a porous substrate, again, such as ceramic. One of the electrodes 18A can be Pt sputtered upon a porous substrate, such as ceramic. The other electrode 18B can be Ag sputtered on ceramic and converted to AgCl electrochemically or by chemical treatment, e.g. by bringing Ag in contact with 1% $FeCl_3$ in 0.1m HCl. One of the electrodes 18B operates as the reference electrode with the other operating as the working electrode 18A in an amperometric sensing measurement, which is well known in the art.

Referring to Figure 2, there is shown another embodiment of the sensor 10 of the present invention. The difference between the embodiment shown in Figure 2 and the embodiment shown in Figure 1 is that in Figure 2, only one of the electrodes 18A is mounted on the substrate 16. The second electrode 18B is mounted directly opposite the first electrode 18A with the layer of chemical 24 therebetween. Thus, in Figure 2, the interstitial fluid passes substantially through the substrate 16 and through the first electrode 18A into the chemical layer 24. The second electrode 18B has one surface in contact with the layer of chemical 24 and a second surface generally opposite thereto. The second electiode 18B is also generally on a porous material. With the first electrode 18A also being of a porous material, the pump 30 can suck the interstitial fluid through the substrate 16 and into the chemical layer at 24.

Referring to Figure 3, there is shown yet another embodiment of the sensor 10 of the present invention. In Figure 3, the two electrodes 18A and 18B have one side thereof mounted on the porous substrate 16. Each of the second side of the electrodes 18A and 18B faces and is in contact with the layer of chemical 24. Thus, in Figure 3, the interstitial fluid passes substantially through the chemical layer 24 (possibly after passing through a layer of second porous material), and contacts the layer of chemicals 24 and the first and second electrodes 18A and 18B. The fluid then passes through the substrate 16. The pump 30 can suck the interstitial fluid through the layer 24 of chemical into the electrodes 18A and 18B and through the substrate 16.

There are many advantages to the integral interstitial fluid of the present invention. The particular advantage is that the volume of fluid sucked from the person or animal can be extremely small. Thus, the entire assembly can be made small, e.g. the size of a wrist watch. For measurement of certain chemical components in the interstitial fluid, such as glucose, the sensor 10 can be worn by a diabetic patient so the glucose measurement can be done "on demand." This will result in a convenient device for the continuous monitoring of glucose in tissue fluid which as known in the prior art, with the glucose in the interstitial fluid correlating to the glucose in blood.

Claims

1. An integral interstitial fluid sensor for application to the skin of a person or an animal for the detection of chemical components of said fluid, said sensor, comprising:

   a substrate of a porous material for the passage of the interstitial fluid therethrough;

   at least two electrodes;

   one of the electrodes has two sides, one side is mounted on said substrate with a second side generally opposite said one side, said electrode is of a porous material for the passage of the interstitial fluid through the two sides;

   a layer of chemical in contact with said second side of said one electrode, said layer comprising a chemical, for reaction with one component of said fluid, mixed in a mediating agent;

   said electrodes for generating an electrical signal in response to the reaction of the one component of said fluid with said layer of chemical;

   detecting means for receiving said electrical signal and for generating a display in response thereto; and

   means for sucking said fluid from the skin into said layer of chemical.

2. The sensor of Claim 1 wherein each of said two electrodes is mounted on said substrate, each electrode has two sides with one side on said substrate and a second side generally opposite thereto, for the passage of the interstitial fluid through said two sides, and with said layer of chemical in contact with said second side of each

of the electrodes.

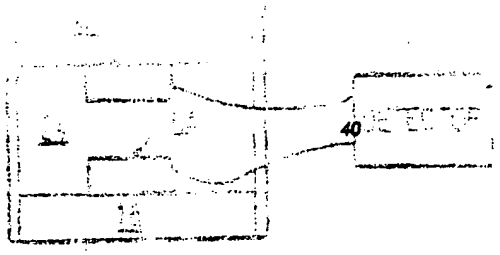
3. The sensor of Claim 1 wherein the other electrode has two sides with one side in contact with said layer of chemical, and a second side, generally opposite said one side, said other electrode for the passage of the interstitial fluid through the two sides.

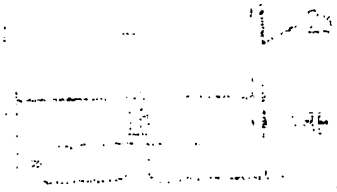
4. The sensor of Claim 1 wherein said substrate is ceramic.

5. The sensor of Claim 1 wherein one of said electrodes comprises Pt on a porous substrate.

6. The sensor of Claim 5 wherein the other electrode is AgCl on a porous substrate.

7. The sensor of Claim 1 wherein said layer of chemical is glucose oxidase and said one component is glucose.





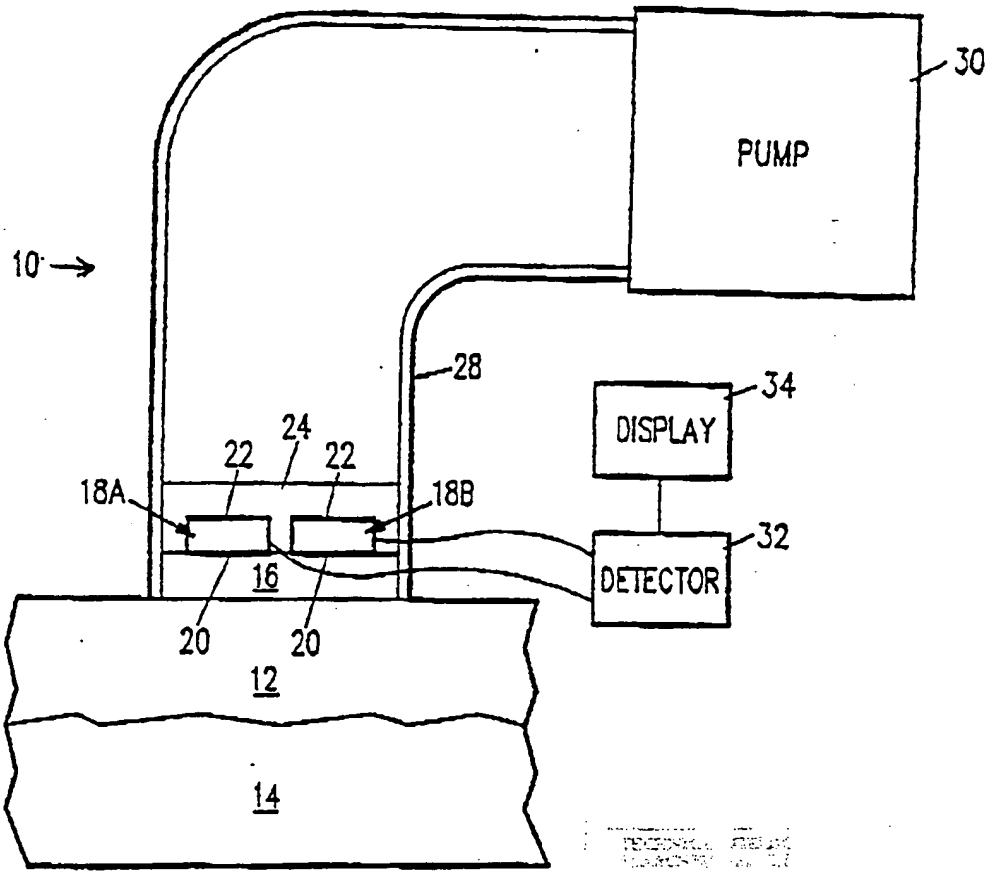


FIG. 1

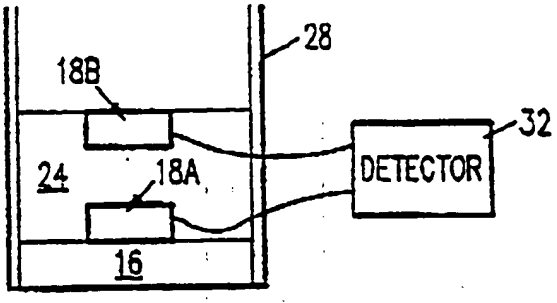


FIG. 2

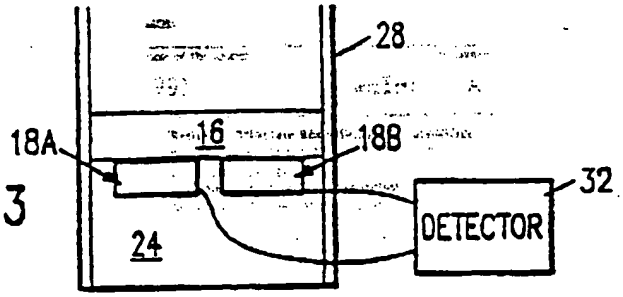


FIG. 3

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EUROPEAN SEARCH REPORT

Application Number

EP 91 30 3469

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	GB-A-1 394 171 (WHITTAKER CORP.) * page 2, lines 14-31; page 3, lines 63-114 *	1	A 61 B 5/00 C 12 M 1/40
A		2,3,5	
X		7	
Y	DE-A-3 713 060 (SIEMENS AG) * column 3, line 34 - column 5, line 7; figure 1 *	1	
A		7	
A	US-A-4 655 880 (CH.-CH. LIU) * column 11, lines 11-69 *	1,5-7	
A	GB-A-2 204 408 (THE PLESSEY COMPANY) * abstract; page 6, lines 16-25; page 9, lines 4-13; figure 3 *	1,5,7	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B 5/00
C 12 M 1/00
C 12 Q 1/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	25-07-1991	WEIHS J.A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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